U.S. SENATE Established 1947
Republican Policy Committee

No. 27 June 16, 2003

S. 1 S The Prescription Drug and Medicare Improvement Act

Calendar No. 138

Reported with an amendment in the nature of a substitute from the Finance Committee on June 13, 2003, by a vote of 16-5; voting 'nay' were Senators Nickles, Lott, Rockefeller, Graham (FL), and Kerry. No written report was issued.

NOTEWORTHY

Note: *Because the Finance Committee issued no written report or summary to date, the information contained in this Legislative Notice is based on Chairman Grassley's mark and modifications to the mark. RPC's description of amendments offered during markup are from Committee staff.*

- By unanimous consent, on June 16, at 2 p.m., the Senate proceeded to the consideration of S. 1 for debate only. S. 1 establishes a comprehensive, permanent prescription drug benefit under the Medicare program, and also creates a new "Medicare Advantage" program, which replaces the current Medicare + Choice program. The new program provides seniors a menu of health plans, with a heavy emphasis on preferred provider organizations (PPOs).

- S. 1 is in response to the Congress's FY 2004 budget resolution, which contained a 10-year, $400 billion Medicare Reserve Fund to provide prescription drug coverage and to strengthen the Medicare program for the long-term.

- On June 11, the Congressional Budget Office issued preliminary cost estimates of the Chairman's mark indicating $399.9 billion over years 2004 - 2013. This estimate does not reflect amendments accepted during the Committee markup, or technical changes made after the markup.

- It is expected that Senators will offer amendments to S. 1 including, but not limited to prescription gap coverage, drug reimportation, generic drug patent changes, preventative health care, health care provider payments, and Medicaid. It is likely there will be Budget Act points of order against most amendments.

- A Statement of Administration Policy, in support of S. 1, is expected to be issued shortly.

HIGHLIGHTS

- **Immediate prescription drug assistance.** Interim assistance would be provided to Medicare beneficiaries using a drug discount card for years 2004 and 2005, which is expected to yield them a savings of between 10 percent and 25 percent. In addition, low-income beneficiaries (defined as those with incomes at or below 135 percent of the federal poverty level[1]) would receive an additional $600 subsidy annually to assist with the purchase of prescription drugs. The discount drug card would expire after 2005.

C **Comprehensive prescription drug coverage.** Beginning in 2006, the bill establishes a voluntary drug benefit that is integrated with other medical benefits for those opting to enroll in private-sector health plans. For beneficiaries choosing to stay in the traditional Medicare program, the benefits would be provided through private "drug only" insurance plans. The value of, and subsidy toward, the prescription drug benefit for beneficiaries in the new "Medicare Advantage" program and traditional Medicare would be equal. The drug benefit would be structured as follows:

	Senior Cost
Monthly Premium	$35
Deductible	$275
Coinsurance	50% beneficiary cost-sharing between $276 and $4,500; and 10% coinsurance applies to all drug spending above the catastrophic limit of $5,800 (beneficiary pays all expenses between $4,500 and $5,800)

C **Choice of integrated health plans.** Beneficiaries electing to enroll in a private integrated plan would do so under the new "Medicare Advantage" program. The new program replaces the current Medicare + Choice program and provides seniors with a choice of health plans, including health maintenance organizations (HMOs), medical savings accounts (MSAs), provider sponsor organizations (PSOs), private fee-for-service (PFFS), and preferred provider organizations (PPOs).

[1]Currently, 135 percent of poverty would be incomes of $12,120 for individuals and $16,360 for couples.

- **Preserve the traditional Medicare program.** Beneficiaries also would have the choice of remaining in traditional Medicare and continuing to receive health care services as they currently do, with the addition of prescription drug coverage.

- **Federal oversight.** S. 1 establishes a new agency, referred to as the Center for Medicare Choices, within the Department of Health and Human Services. It would be responsible for administering new benefit and health plan options.

- **Rural Health Care Provider relief.** The measure contains about $25 billion over 10 years in new funding for rural health care providers. This funding is offset by changes in clinical laboratory coinsurance amounts, durable medical equipment and certain orthotic payments, the average wholesale price payable for drugs and biologicals, Customs user fees, and increased Medicare Part B deductibles. CBO estimates these offsets to total about $66 billion over 10 years.

- **Regulatory relief.** The bill includes new Medicare rulemaking and appeal process reforms for health care providers.

- **Medicaid and S-CHIP changes.** S. 1 includes increased funding to the states for Medicaid disproportionate share hospital (DSH) payments. It also provides federal coverage of legal immigrant children and pregnant women under Medicaid, and allows them to qualify under the State Child Health Insurance Program (S-CHIP) for years FY2005-2007.

BACKGROUND

Medicare is a nationwide health insurance program that offers health insurance protection for 40 million older Americans and disabled persons. The program provides broad coverage for the costs of many, primarily acute, health services. However, there are many gaps in program coverage, the most notable being that Medicare provides very few preventative health care benefits, no catastrophic coverage for long-term acute illnesses, and no coverage for outpatient prescription drugs. By contrast, today's private health insurance market, including plans offered under the Federal Employees Health Benefits Program (FEHBP), include many such benefits.

An antiquated benefit package is not the only reason policymakers suggest the need to strengthen the program. A look at the following numbers bears this out:

- Growing demographic pressures (enrollment is expected to reach 77 million by 2031).

- Rising medical costs (Medicare spending increased by an annual average of 9.6 percent per beneficiary between 1968 and 2000[2]).

- Increased longevity of older Americans (in 2000, the number of seniors over the age of 85 was 34 times larger than it was a century before[3]).

- Accelerating demand on Hospital Insurance Trust Fund and Supplementary Medical Insurance Trust Fund, e.g., hospital and physician services (combined expenditures as a percentage of the Gross Domestic Product are projected to increase rapidly, from 2.6 percent in 2002 to 5.3 percent by 2035 and then to 9.3 percent by 2077[4]).

Given the statistics and inadequate benefit structure, Congress has considered reforming the Medicare program on several occasions. The issue was debated extensively in the 106th Congress. The FY 2002 budget resolution adopted by Congress provided up to $300 billion over the years 2003-2011 for Medicare reform and a prescription drug benefit. While Congress failed to pass a budget resolution in FY 2003, both the House and Senate considered legislation during the summer of 2002. Debate picked up again this year with the passage of the FY 2004 budget resolution, which contains a $400 billion Medicare Reserve Fund over the years 2004-2013 for the purpose of providing prescription drug coverage and strengthening the program for the long-term.

The House is expected to consider Medicare prescription drug legislation as well. The House Ways and Means and Energy and Commerce Committees tentatively have scheduled markups early this week. The House measure is expected to cost $400 billion over 10 years although no official estimates from CBO have been issued as of last week. The proposal includes a similar $35 monthly premium but a slightly lower deductible, $250, as compared to the Senate bill. In general, the House measure provides more coverage up-front for beneficiary drug expenses (80 percent for the first $2,000). By contrast, the Senate proposal only covers half of beneficiary drug expenses, but up to a much higher limit ($4,500). These are just some of the differences between the two bills.

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[2]"Report to the Congress: Medicare Payment Policy," Medicare Payment Advisory Commission, March 2003.

[3]Administration on Aging, "Profile of Older Americans: 2002," December 2002.

[4]2003 Medicare Board of Trustees Report, March 17, 2003.

BILL PROVISIONS

S. 1 was introduced on June 11, 2003, by Majority Leader Frist on behalf of Chairman Grassley and Ranking Minority Member Baucus. The Committee on Finance ordered the bill reported by a vote of 16-5 on June 12, with an amendment in the nature of a substitute.

TITLE I. MEDICARE PRESCRIPTION DRUG BENEFIT

Starting in 2004, Medicare beneficiaries would have access to a discount card for prescription drug purchases. Projected savings from the card for consumers would range between 10 percent and 25 percent. A $600 subsidy would be applied to the card offering additional assistance for low-income beneficiaries (defined in the bill as at or below 160 percent of the federal poverty level).

Effective January 1, 2006, a new optional benefit would be established under Medicare Part D. Coverage includes prescription drugs, biological products, insulin, and certain vaccines. Beneficiaries could choose either "standard coverage" or actuarially equivalent coverage. In 2006, standard coverage would have a $35 monthly premium, $275 deductible, 50 percent cost-sharing for expenses between $276 and $4,500, and then no coverage until the beneficiary had reached a catastrophic limit of $5,800. However, the true out-of-pocket maximum expenditure (also referred to as TROOP) for any individual would be $3,700, after calculating for the deductible and federal covered amounts. A 10-percent coinsurance amount would apply to any expenses thereafter. Each of the premium, deductible, and cost-sharing amounts are indexed for inflation.

Moreover, out-of-pocket expenses are defined as those paid by the individual or Medicaid and state pharmaceutical assistance amounts paid on behalf of a low-income individual. Costs reimbursed by other supplemental insurance plans are not counted. After January 1, 2006, current Medigap "drug only" policies will no longer be available. However, beneficiaries may continue to purchase non-drug supplemental policies.

Dual eligibles (those who qualify for Medicaid and Medicare) would remain in the Medicaid program for prescription drug coverage. S. 1 provides states with additional assistance by assuming Medicare Part A (hospital services) cost-sharing expenses. This assistance is available to those states that have expanded coverage above the minimum income level for low-income Medicare and Medicaid enrollees. Finance Committee staff estimate the provision would cost $3.5 billion over 10 years, rewarding approximately 19 states.

Second, states would be relieved of Part B (physician services) premiums currently paid under Medicaid. S. 1 also provides enhanced matching rates to states for administrative costs associated with making eligibility determinations for low-income subsidies, including system upgrades. In addition, the

measure includes additional assistance to beneficiaries with incomes below 160 percent of the poverty level at increasingly different levels. Assistance is based on the following categories:

- Individuals below 100% poverty level meeting federally designated Qualified Medicare Beneficiary (QMB) eligibility standards ($8,980 single/$12,120 couple)
  - no deductible and no monthly premium
  - 2.5% coinsurance for drug spending to benefit gap of $4,500
  - 5% coinsurance for drug spending between $4,501 and the catastrophic limit
  - 2.5% coinsurance for drug spending above the catastrophic

- Individuals between 100-135% poverty level meeting designated Specified Low-Income Medicare Beneficiary (SLMB) and Qualified Individuals (QI-1) eligibility standards ($12,120 single/$16,360 couple)
  - no deductible and no monthly premium
  - 5% coinsurance for drug spending to benefit gap of $4,500
  - 10% coinsurance for drug spending between $4,501 and the catastrophic limit
  - 2.5% coinsurance for drug spending above the catastrophic

- Non-dual eligibles and others below 160% poverty level with no asset test ($13,470 single/$18,180 couple)
  - $50 deductible
  - sliding premium (no premium at 135% poverty, full premium at 150%)
  - 10% coinsurance for drug spending to benefit gap of $4,500
  - 20% coinsurance for drug spending between $4,501 and the catastrophic limit
  - 10% coinsurance for drug spending above the catastrophic

Under the new drug delivery model, insurers would bear partial risk for drug spending, which would be moderated through reinsurance and risk corridors. In the first two years of the drug benefit (2006 and 2007), insurers would bear a smaller portion of risk for total drug spending. Beneficiaries would have the choice of two plans in a given area. Approved plans would receive a two-year contract.

If two plans fail to materialize, then the federal government would annually contract with an entity to provide Part D coverage. The fallback plan would bear performance risk only. Standard coverage and national premium levels, adjusted for differences in drug utilization, would apply.

TITLE II. MEDICARE ADVANTAGE

Beginning in 2006, beneficiaries electing to enroll in a private plan participating in Medicare could do so under the new "Medicare Advantage" program. The program would replace the current Medicare + Choice program (Part C) with a choice of several health plan options. The Medicare Advantage plan could be a coordinated care plan such as an HMO, PSO, or PPO. Other options include MSAs and PFFS plans. The new program would place a heavy emphasis on PPOs since they

offer beneficiaries a much wider choice of health care providers while also coordinating care effectively, especially for those with multiple, chronic conditions. PPOs essentially are a "hybrid" between fee-for-service plans (whereby insurance companies pay the fees set by hospitals and doctors), and managed care plans (which manage patient care through contracts with certain providers willing to accept negotiated payment rates). PPOs contract with providers, but usually the number of participating providers is greater than most comparable HMO networks. PPOs also have more generous out-of-network benefits compared to HMOs.

All health plans would be required to offer at least the standard drug benefit. Also, health plans would be required to offer Medicare Part A and B benefits which will be the basis of their reimbursement by the federal government. Plans would be required to provide catastrophic benefits for traditional medical benefits, and they would be encouraged to offer disease management, chronic care, and quality improvement programs to their enrollees.

To help ensure participation in rural and urban areas equally, PPOs would submit bids on a regional basis. There would be at least 10 regions. Each region would have to include at least one state. The Secretary could not divide states so that portions of the state were in different regions. To the extent possible, the Secretary would include multi-state metropolitan statistical areas in a single region except where necessary to establish a region of such size and geography needed to maximize PPO participation.

PPOs would submit bids for coverage of required benefits, with assumptions about possible enrollees. Payments to the regional PPO plans then would be calculated using a benchmark amount to ensure that the payment level is no higher than local fee-for-service costs, or the current law HMO rate, whichever is higher of the two. Growth in HMO floor payment rates would be limited to the growth in the consumer price index (CPI) starting in 2014. Bids that are equal to or exceed the benchmark would be paid the benchmark rate. Bids below the benchmark would receive the bid amount. In addition, the difference between the bid and the benchmark would be split 75 percent for the beneficiary and 25 percent back to the federal government. Payments would be offset by any premium reductions elected by the plan. The Secretary is instructed to accept the three lowest-cost credible bids in a region. The federal government would share the risk with insurance companies and PPOs for any potential profits and/or losses through the use of risk corridors. Shared risk only would be available during the first two years of implementation (2006 and 2007).

T**ITLE III. CENTER FOR MEDICARE CHOICES**

No later than March 1, 2004, the Secretary must establish a new Center for Medicare Choices within the Department of Health and Human Services. The agency would be responsible for administering benefits under Medicare Parts C and D. The Center's administrator would be appointed by the President and confirmed by the Senate for a five-year term.

The agency also must also establish an ombudsman office to make Medicare eligibility determinations, enroll beneficiaries, and provide benefit and appeals information. In addition, a

Medicare Competitive Policy Advisory Board must be created to advise, consult, and make recommendations to the Administrator concerning administration and payment policies. There shall be seven board members serving three terms, of which three would be appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but restricted to a maximum of eight years of service.

TITLE IV. MEDICARE FEE-FOR-SERVICE PROVISIONS

During the markup, Chairman Grassley modified the chairman's mark to address "pay-go" concerns by revising the effective date for several health care provider provisions. These provisions are similar to an amendment that Chairman Grassley offered during floor consideration of The Jobs and Growth Tax Relief Reconciliation Tax Act of 2003 (*for additional information, please refer to Senate Record Vote Analysis for amendment no. 594, offered on May 15, passed 86-12, but later struck during the tax reconciliation conference committee*).

The Chairman's mark originally proposed implementing the following changes at the start of FY2004. However, the bill as reported modified the effective date to FY2005 for most provisions. In some cases, the provisions were phased-in for FY2004 and fully implemented in FY2005. The provisions are:

- Full and Permanent Equalization of the Standardized Payment Amount
- Equalize Medicare Disproportionate Share Payments
- Assistance for Low-Volume Hospitals
- Revision of the Labor Share to 62%
- Extend Hold Harmless for Rural Hospitals under Outpatient Prospective Payment System
- Critical Access Hospital (CAH) Improvements and other changes
  - Flexibility in CAH bed limit
  - Improved payments for CAH ambulance services
  - Coverage for emergency on-call providers
  - Reinstate Periodic interim payments (PIP)
  - Exclude CAHs from the wage index calculation
- 5-percent add-On Payment to Rural Home Health Agencies
- 5-percent add-on for clinic and ER visits for small rural hospitals
- 5-percent increase for rural ground ambulance trips
- Exclude services provided by Rural Health Clinic-based practitioners from SNF consolidated billing
- Make Medicare Incentive Payment 10% bonus payments in rural HPSAs automatic
- 2-year extension of reasonable cost payments for lab tests in sole community hospitals
- Set work, practice expense and malpractice geographic indices for physicians at 1.0

Offsets (CBO preliminary estimates are $65.9 billion over ten years):

- Collect deductible and coinsurance for clinical laboratory services performed in physician offices and hospital outpatient departments
- Seven-year freeze in CPI for durable medical equipment and certain orthotic items
- Beginning January 1, 2004, limit payment for currently covered oncology drugs to the lesser of the average wholesale price (AWP) or 85 percent of the listed AWP as of April 1, 2003.
- Extend Customs User fees
- Increase Medicare Part B deductible

TITLE V. REGULATORY RELIEF

S. 1 includes several rulemaking and regulatory relief changes for health care providers participating in the Medicare program. Currently, the Medicare program contains over 130,000 pages of rules and regulations. These policies often change erratically or, in some cases, languish for years. As a result, S. 1 contains a series of provisions to help providers comply with program mandates.

For instance, the measure bars retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. While there is strong presumption against retroactive rulemaking as a result of case law, there is no explicit statutory instruction currently.

The Secretary also would be required to publish a final regulation within 12 months of releasing an interim final regulation rather than depend on the interim rule for its final status. In general, proposed regulations are announced in the *Federal Register* with at least 30 days to solicit public comment before issuing the final regulation. However, in some cases, such interim final rules have lasted for years, leaving providers to wonder if a subsequent (and a more final) regulation is expected at a later date.

S. 1 requires the Secretary to report to Congress concerning legal and regulatory inconsistencies, and to make recommendations for legislative or administrative action. It also prohibits any penalty or interest imposed on providers or suppliers if they reasonably relied on written guidance. In addition, processes must be developed, permitting providers and suppliers to correct minor claims errors. By contrast, the current Medicare program requires providers to pursue a lengthy appeals process before adjusting any payment claim despite the level of the error. Such processes also have affected the way in which providers, suppliers, or beneficiaries obtain judicial reviews of certain regulations. Today's administrative appeals must be exhausted prior to such review. However, S. 1 expedites these procedures in cases whereby the Medicare Appeals Board determines it does not

have the authority to decide the question of law or regulation and where material facts are not in dispute.

TITLE VI. OTHER PROVISIONS

Title VI of S. 1 contains a handful of provisions mostly affecting the Medicaid program. First, the measure increases state Medicaid disproportionate share hospital (DSH) allotments. Currently, hospitals serving a large number of uninsured patients and Medicaid recipients receive additional DSH payments to help defray the cost of uncompensated care. S. 1 includes two changes concerning such payments: 1) extension of increased DSH funding for FY2004 as established by the Beneficiary Improvement and Protection Act of 2000; and 2) increased DSH monies for certain states with extremely low allotments.

In addition, S. 1 provides federal coverage of legal immigrant children and pregnant women under Medicaid, and allows them to qualify under the State Child Health Insurance Program (S-CHIP). Under current law, states have the option to offer such coverage. However, S. 1 expands federal coverage for such services provided during FY2005-2007. Finance Committee staff predict that the provision would cost approximately $350 million over the three-year period.

Title VI also includes an increase in civil penalties under the False Claims Act and the Social Security Act, and extends Customs user fees until September 30, 2013.

Finally, Title VI authorizes $49 million for a new, cancer-related infrastructure loan program. Funding would start July 1, 2004, and last until FY2008. Eligible projects include those located in a State that has a population of less than 3 million; and are engaged in research, prevention, and treatment of cancer.

ADMINISTRATION POSITION

A Statement of Administration Policy in support of S. 1 is expected to be issued early this week.

COST

On June 11, CBO issued preliminary cost estimates of S. 1, projecting that the bill would cost $399.9 billion over years 2004-2013. Recall that this estimate does not reflect amendments accepted during the committee markup, or technical changes made after the markup.

OTHER VIEWS

Letters of support to the Majority Leader and Chairman Grassley include, but are not limited to, the National Association of Manufacturers, Business Roundtable, Healthcare Leadership Council, National Association of Health Underwriters, National Council on the Aging, Health Insurance Association of America, American Hospital Association, and the Geographic Equity in Medicare Coalition.

According to the Republican Conference, groups that oppose S. 1 include Public Citizen, Families USA, Alliance for Retired Americans, and American Federation of Labor-Congress of Industrial Organizations (AFL-CIO). The American Association of Retired Persons (AARP) has been quoted supporting passage of a prescription drug benefit in general but continues to advocate for greater federal spending to minimize the drug coverage gap between $4,500 and $5,800, as well as further reduced out-of-pocket drug costs.

POSSIBLE AMENDMENTS

Hagel-Ensign Plan

An amendment based on S. 778 may be offered by Senators Hagel and Ensign to make prescription drug discount cards available to all Medicare participants. The bill targets low-income seniors and those with excessively high prescription drug costs, adding protection from unlimited out-of-pocket costs through a cap on expenditures. For low-income seniors, the bill provides nearly 100-percent coverage of any prescription drug costs above $1,500. For upper-income seniors, the limit is set much higher. Below is the scale:

Out-of-Pocket Limit	Poverty Level
$1,500	< 200% of Poverty Level
$3,500	Between 200% and 400%
$5,500	Between 400% and 600%
20% of Income	Above 600%

Last year's CBO estimate projected that the measure would cost $296 billion over 10 years. Sponsors of the bill have not received a score from CBO as of press time, but expect a similar cost estimate.

Amendments Offered and Defeated During Committee Markup

The following amendments were offered and defeated (some by record vote, some by voice vote) during the committee markup. It is possible they (or some iteration thereof) could be offered during floor consideration.

Graham(FL)/Rockefeller	Direct government administration of drug benefit.
Daschle/Conrad	Replace private drug insurance coverage with long-term government administration of drug benefit.
Rockefeller/Kerry	Displacing more private employer and union retiree health coverage with tax-payer financed Medicare coverage.
Rockefeller/ Bingaman/ Lincoln	Increasing Federal share of Medicaid funding.
Dashle/Lincoln	Setting a national standard premium for private health plans.
Daschle	Capping premium rates with national price caps.
Graham (FL)/Kerry	Further increase Federal spending for the drug benefit.

Bingaman/Kerry	Guarantee first-dollar drug coverage.
Rockefeller/Kerry	Add new, expensive medical benefits to the traditional Medicare program at the expense of improving new, private PPO Medicare options.

Other Possible Amendments

Dorgan/Stabenow	Allow reimportation into the U.S. of drugs approved by the FDA and exported to Canada..
Schumer/McCain	Administrative procedures for generic drug patents (bipartisan agreement recently reached in HELP Committee).
Rockefeller	Narrow Medicare prescription drug coverage gap.
Johnson	Drug price controls.
Stabenow	Limits on drug company advertising.

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